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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/565,484 | 01/17/2006 | Nai-Kong V. Cheung | 639-C-PCT-US | 2140 |

7590 12/17/2008
Albert Wai Kit Chan
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| EXAMINER |
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OLSON, ERIC

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| ART UNIT | PAPER NUMBER |
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1623

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| MAIL DATE | DELIVERY MODE |
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12/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/565,484 | CHEUNG, NAI-KONG V. | |
| | Examiner | Art Unit | |
| | Eric S. Olson | 1623 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-17, 19-25 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-17, 19-25 and 27-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/10/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 10, 2008 has been entered.

This office action is a response to applicant's communication submitted October 10, 2008 wherein claims 14 and 22 are amended and claims 18 and 26 are cancelled. This application is a national stage application of PCT/US04/23099, filed July 16, 2004, which is a continuation in part of US application 10/621027, currently pending, filed July 16, 2003, which is a continuation in part of PCT/US02/01276, filed January 15, 2002, which claims benefit of provisional application 60/261911, filed January 16, 2001.

Claims 14-17, 19-25, and 27-29 are pending in this application.

Claims 14-17, 19-25, and 27-29 as amended are examined on the merits herein.

Priority

Currently, the application claims priority to US application 10/621027, PCT international applications PCT/US04/23099 and PCT/US02/01276, and provisional application 60/261911. However, the applications PCT/US02/01276, 10/621027, and 60/261911 fail to provide written description under 35 USC 112, first paragraph for instant claims 14-17, 19-25, and 27-29 because the applications do not disclose beta-

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glucans having side chains of two or more saccharides linked by a (1,3) linkage.

Rather, these parent applications disclose barley glucans having a straight chain containing a mixture of (1,3) and (1,4) linkages, as well as fungal glucans of indeterminate composition. Therefore the effective filing date of claims 14-17, 19-25, and 27-29 is seen to be the filing date of PCT/US04/23099, filed July 16, 2004.

Applicant's amendment, submitted October 10, 2008, with respect to the rejection of instant claims 18 and 26 under 35 USC 112, second paragraph for reciting a chemical structure having an undefined variable, has been fully considered and found to be persuasive to remove the rejection as the rejected claims have been cancelled. Therefore the rejection is withdrawn.

Applicant's amendment, submitted October 10, 2008, with respect to the rejection of instant claims 14-29 under 35 USC 103(a) for being obvious over Yan et al. in view of Donzis et al., has been fully considered and found to be persuasive to remove the rejection as Yan et al. is not seen to teach glucans having the same side chains recited in the instant claims. Therefore the rejection is withdrawn.

The following new grounds of rejection are introduced:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 14-17, 19-25, and 27-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Ostroff et al. (US pre-grant publication 2006/0165700, cited in PTO-1449)

Ostroff et al. discloses a method of antitumor therapy in which complement-activating antibodies that bind to the complement receptor CR3 are coadministered with insoluble beta glucan. (p. 2 paragraph 0010) Preferred antibodies include monoclonal antibodies such as trastuzumab, rituximab, and cetuximab. (p. 3 paragraph 0015) According to the FDA-approved labeling for these antibodies, (References included with PTO-892, included solely to elucidate the teaching of Ostroff et al. and not as a secondary reference) trastuzumab binds to the protein HER2 (p. 1 last paragraph of label) and is used to treat metastatic breast cancer, (p. 4 paragraph 4 of label) rituximab binds CD20 (p. 1 left column fourth paragraph of label) and is used to treat non-Hodgkin's lymphoma, (p. 1 right column third paragraph of label) and cetuximab binds the protein EGFR (p. 1 first paragraph of label) and is used to treat colorectal carcinoma. (p. 6 second paragraph of label) Beta glucans used in this invention can include whole glucan particles isolated from cell walls by the method of US patent 4810646. (p. 4 paragraph 0044) Note that according to p. 12 lines 9-22 of the specification as originally filed and p. 3 paragraph 3 of Applicant's arguments submitted October 10, 2008, the claimed beta glucans having the claimed branching

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characteristics are characterized by having been prepared by the process of US patent 4810646 involving extraction with alkali followed by extraction with acid, said patent being incorporated by reference into Ostroff et al. The glucan described in US patent 5223491 is also disclosed by Ostroff et al. to be included as a yeast cell wall beta(1,3)(1,6) glucan. (p. 4 paragraph 0046) The glucans can be included as orally bioavailable compositions. (p. 4 paragraph 0047) Yeast cells such as *Saccharaomyces cerevisiae* are a preferred source of beta glucan particles. (p. 5 paragraph 0049) Because the beta glucan is prepared by the same method as those in the claimed invention, it inherently possess the same properties such as molecular weight, cytokine induction and antibody-mediated cytotoxicity as recited in instant claims 17, 25, and 29. The antibodies and beta glucans can be co-administered. (p. 8 paragraph 0083) Various oral and other dosage forms can be prepared to administer the therapeutic compounds. (p. 8 paragraph 0084 - p. 9 paragraph 0090) Therefore the dosage form administered when the two components are co-administered is a composition according to the instant claims.

Therefore Ostroff et al. anticipates the claimed invention.

Conclusion

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
12/12/2008

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623